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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/586,264

Applicant(s)

SCHWEIZER ET AL.

Examiner

QIUWEN MI

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2008.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
4a) Of the above claim(s) 1-7 and 27-30 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 8-26 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 18 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/5508)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election of Group II, claims 8-26, in the reply filed on 7/28/08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-30 are pending. Claims 1-7, and 27-30 are withdrawn from further consideration as being drawn to non-elected inventions. **Claims 8-26 are examined on the merits.**

Claim Objections

Claims 8, 19, 20 are objected to because of the following informalities: Claims 8, 19, and 20 recite "90% wt% (N x 6.25) d.b.", and it is improper to use the abbreviation "d.b." in the claims, and Applicant is required to spell out the abbreviation.

Specification/Abstract Objections

Specification

The disclosure is objected to because of the following informalities: The specification recites "novel" on pages 1-5, 9, 16, 20, 27, and 30. It is suggested that the term "novel" be deleted from the language of the specification. Once the determination of the novelty of a claimed invention has been established and the disclosure of the invention made public and/or patented, the claimed invention is no longer novel or new, since the scope of the invention no longer embraces what is considered "novel". Thus, the incorporation of the term "novel" into the language of the specification is not appropriate. Correction is required.

Abstract

The abstract of the disclosure is objected to for the following reasons: The abstract recites "novel canola protein" in lines 1, 7, and 13. It is suggested that the term novel be deleted from the language of the abstract. Once the determination of the novelty of a claimed invention has been established and the disclosure of the invention made public and/or patented, the claimed invention is no longer novel, since the scope of the invention no longer embraces what is considered "novel". Thus, the incorporation of "novel" into the language of the abstract is not appropriate. Appropriate correction is required. Correction is required. See MPEP § 608.01(b).

Double Patent Rejections

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

1. Claims 8-26 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 8-26 of copending Application No. 11/272,705. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Logie et al (US 2004/0034200) in view of Hiron (US 2003/0224099).

Logie et al teach that the PMM (gelatinous gluten-like protein micellar mass)-derived canola protein isolate preferably has a protein component content of about 88 to about 98 wt % of 7S protein, about 1 to about 10 wt % of 12S protein and 0 to about 6 wt % of 2S protein while the supernatant-derived canola protein isolate preferably has a protein component content of about 70 to about 95 wt % of 2S protein, about 5 to about 30 wt % of 7S protein and 0 to about 2

wt % of 12S protein [0012] (thus an increased proportion of 2S canola protein). The present invention provides a canola protein isolate composition comprising (1) a first canola protein isolate having a protein content of at least about 90 wt %, preferably at least about 100 wt %, on a dry weight basis and at a Kjeldahl nitrogen conversion of N.times.6.25 and which exhibits a protein profile which is about 60 to about 98 wt % of 7S protein, about 1 to about 15 wt % of 12S protein and 0 to about 25 wt % of 2S protein [0016]. The aqueous protein solution resulting from the high or low pH extraction step then is pH adjusted to the range of about 5 to about 6.8, preferably about 5.3 to about 6.2 [0048] . The concentrated protein solution resulting from the concentration step and optional defatting step then is diluted to effect micelle formation by mixing the concentrated protein solution with chilled water having the volume required to achieve the degree of dilution desired. Depending on the proportion of canola protein desired to be obtained by the micelle route and the proportion from the supernatant, the degree of dilution of the concentrated protein solution may be varied. With higher dilution levels, in general, a greater proportion of the canola protein remains in the aqueous phase [0055]. When it is desired to provide the greatest proportion of the protein by the micelle route, the concentrated protein solution is diluted by about 15 fold or less, preferably about 10 fold or less [0056]. The chilled water with which the concentrated protein solution is mixed has a temperature of less than about 15.degree. C., generally about 3.degree. to about 15.degree. C., preferably less than about 10.degree. C., since improved yields of protein isolate in the form of protein micellar mass are attained with these colder temperatures at the dilution factors used [0057]. The supernatant from the dilution step, following removal of the PMM, is concentrated to increase the protein concentration thereof. Such concentration is effected using any convenient selective membrane

technique, such as ultrafiltration, using membranes with a suitable molecular weight cut-off permitting low molecular weight species, including the salt and other non-proteinaceous low molecular weight materials extracted from the protein source material, to pass through the membrane, while retaining canola protein in the solution. Ultrafiltration membranes having a molecular weight cut-off of about 3000 to 10,000 daltons, having regard to differing membrane materials and configuration, may be used. Concentration of the supernatant in this way also reduces the volume of liquid required to be dried to recover the protein. The supernatant generally is concentrated to a protein concentration of about 100 to about 400 g/L, preferably about 200 to about 300 g/L, prior to drying. Such concentration operation may be carried out in a batch mode or in a continuous operation, as described above for the protein solution concentration step [0073]. The concentration step may be effected in any convenient manner consistent with batch or continuous operation, such as by employing any convenient selective membrane technique, such as ultrafiltration or diafiltration, using membranes, such as hollow-fibre membranes or spiral-wound membranes, with a suitable molecular weight cut-off, such as about 3000 to about 50,000 daltons, having regard to differing membrane materials and configurations, and, for continuous operation, dimensioned to permit the desired degree of concentration as the aqueous protein solution passes through the membranes [0050]. The molecular weight cut-off of the membrane is usually chosen to ensure retention of a significant proportion of the protein in the solution, while permitting contaminants to pass through having regard to the different membrane materials and configurations [0053]. The salt solubilization of the protein is effected at a temperature of at least about 5.degree. C. and preferably up to about 35.degree. C., preferably accompanied by agitation to decrease the solubilization time, which is

usually about 10 to about 60 minutes. It is preferred to effect the solubilization to extract substantially as much protein from the oil seed meal as is practicable, so as to provide an overall high product yield [0033]. In a second set of experiments, 500 mL of water with no salt added was first heated to 60.degree. C. on a hot plate stirrer and then 50 g of canola oil seed meal which had been low temperature toasted at 100.degree. C. to remove residual solvent were added and stirred for 15 minutes while the temperature was maintained. The extract was separated from the spent meal by centrifugation at 5000.times.g for 10 minutes (thus about 5-10 min) [0136] (thus heat treating the aqueous solution to cause precipitation of 7S canola protein, removing degraded 7S protein from aqueous solution; separating said aqueous protein solution from residual oil seed meal). The clarified aqueous protein solution is pumped by line 26 through ultrafiltration membrane 28 to produce a concentrated protein solution as the retentate in line 30 with the permeate being recovered by line 32. The concentrated protein solution is passed into a precipitation vessel 34 containing cold water fed by line 36. Protein micellar mass formed in the precipitation vessel 34 is removed by line 38 and passed through a spray dryer 40 to provide dry canola protein isolate 42 [0095]. The settled isolate is separated from the residual aqueous phase or supernatant, such as by decantation of the residual aqueous phase from the settled mass or by centrifugation. The PMM may be used in the wet form or may be dried, by any convenient technique, such as spray drying, freeze drying or vacuum drum drying, to a dry form. The dry PMM has a high protein content, in excess of about 90 wt % protein, preferably at least about 100 wt % protein (calculated as Kjeldahl N.times.6.25), and is substantially undenatured [0064]. The aqueous protein solution then is concentrated to increase the protein concentration thereof while maintaining the ionic strength thereof substantially constant [0049].

Logic et al do not teach a canola protein isolate consisting predominantly of 2S protein, neither do Logic et al explicitly teach the claimed temperature for heat treatment, the claimed amount of molecular weight-cut-off of the membrane, and the claimed amount of 7S protein to be degraded.

Hiron et al teach that in one aspect of the present invention, there is provided in a food composition comprising a foodstuff and at least one component providing functionality in said food composition, the improvement which comprises at least partially replacing said at least one component by a substantially undenatured canola protein isolate having a protein content of at least about 90 wt %, as determined by Kjeldahl nitrogen x 6.25 on a dry weight basis, said canola protein isolate exhibiting a protein profile which is about 60 to about 95 wt % of 2S protein (thus predominantly of 2S protein); about 5 to about 90 wt % of 7S protein; 0 to about 5 wt % of 12S protein [0015]. Hiron et al also teach that the canola protein isolate may be utilized in each of these applications to replace the protein commonly used to provide the specific functional properties. In general, the canola protein isolate can replace or extend the existing protein product. In addition, the canola protein isolate has a high quality amino acid profile, bland flavour profile and does not possess detrimental flavour characteristics nor nutritional factors which would adversely affect its employment in food product applications [0019].

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the 2S predominant canola protein from Hiron et al since Hiron et al

teach that the canola protein isolate can replace or extend the existing protein product. And it has a high quality amino acid profile, bland flavour profile and does not possess detrimental flavour characteristics nor nutritional factors which would adversely affect its employment in food product applications. Since both of the invention of Logie et al and Hiron et al yielded beneficial results in making canola protein isolate, one of ordinary skill in the art would have been motivated to make the modifications and combine two inventions together. Regarding the limitation to the claimed temperature for heat treatment, the claimed amount of molecular weight-cut-off of the membrane, or the claimed amount of 7S protein to be degraded, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

QM

/Michele Flood/
Primary Examiner, Art Unit 1655